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5
**STATE OF WASHINGTON
KING COUNTY SUPERIOR COURT**

6 STATE OF WASHINGTON,

7 Plaintiff,

8 v.

9 MCKESSON CORPORATION,
10 CARDINAL HEALTH INC., and
11 AMERISOURCEBERGEN
12 DRUG CORPORATION,

13 Defendants.

NO.

COMPLAINT FOR INJUNCTIVE
AND OTHER RELIEF UNDER
THE CONSUMER
PROTECTION ACT, RCW
19.86, PUBLIC NUISANCE,
AND NEGLIGENCE

14 **I. INTRODUCTION**

15 1.1 On average, two Washingtonians die each day from opioid
16 overdoses. Between 2006 and 2017, opioid overdoses killed more than 8,000
17 Washingtonians, more than either car accidents or firearms. These deaths are
18 attributable to a flood of prescription opioids into the state over the last two
19 decades. Billions of prescription opioid pills have been pumped into Washington,
20 including 112 million daily doses of prescription opioids in 2011 alone – enough
21 for a 16-day supply for every woman, man, and child in the state. As of 2017,

1 || four Washington counties had more opioid prescriptions than people – in 2015,
2 || the number was twice that.¹

3 1.2 This enforcement action seeks to protect the public from unfair
4 practices in the distribution of opioids – dangerous and deadly drugs that are
5 ravaging Washington’s communities and overwhelming public resources.²

6 1.3 Because of the dangers posed by opioids, even when used legally for
7 medical purposes, the prescription and distribution of opioids is heavily regulated
8 under the federal Controlled Substances Act, 21 U.S.C. § 801 *et seq.*, (CSA) and
9 Washington state law.

10 1.4 These laws create obligations for distributors to prevent the
11 diversion of opioids from legitimate, medical uses to illegitimate uses.

12 1.5 Among other things, federal and state law require distributors to
13 effectively control their supply chains to prevent diversion, and to identify,
14 report, and suspend suspicious orders of opioids.

15 1.6 Distributors also have obligations under the common law to exercise
16 reasonable care in the conduct of their business and to not create a public
17 nuisance by unreasonably interfering with public health and safety via the
18 widespread, uncontrolled distribution of dangerous, addictive drugs.

²⁰ U.S. County Prescribing Rates, 2017, available at
21 <https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html>; U.S. County Prescribing Rates,
2015, available at <https://cdc.gov/drugoverdose/maps/rxcounty2015.html>.

² Executive Order 16-09, Addressing the Opioid Use Public Health Crisis (Oct. 7, 2016) available at http://www.governor.wa.gov/sites/default/files/exe_order/eo_16-09.pdf.

1 1.7 Defendants McKesson Corporation, Cardinal Health, Inc., and
2 AmerisourceBergen Drug Corporation are drug distributors who account for the
3 majority of opioids shipped into the State of Washington. They drove the opioid
4 epidemic by repeatedly filling and failing to report “suspicious orders” in
5 violation for federal, state, and common law obligations. Meanwhile, they made
6 billions of dollars feeding the opioid epidemic. This lawsuit aims to hold them
7 responsible for the foreseeable, foreseen, and ongoing consequences of pushing
8 opioids in staggering numbers throughout our State, particularly after it became
9 evident that opioids had caused and were continuing a national epidemic.

10 1.8 This public lawsuit is brought because opioids are unique in the
11 scope of deaths and cost. The U.S. Department of Health and Human Services
12 reported that 47,600 people died of an opioid overdose in 2017. That year more
13 than 11.4 million people misused prescription opioids, including 2 million people
14 for the first time.³ The crisis costs our economy tens of billions annually.⁴

15 1.9 This public lawsuit is brought because the origin of the opioid
16 epidemic is unique. As Washington public health officials have noted, opioid use

³ The U.S. Opioid Epidemic, US. Department of Health & Human Services (Jan. 2019), available at <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

⁴ Florence, Curtis S. PhD; Zhou, Chao PhD; Luo, Feijun PhD; Xu, Likang MD, *The Economic Burden of Prescription Opioid Overdose, Abuse and Dependence in the United States, 2013*, 54(10):901-906, Med Care (Oct. 2016) available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5975355/>.

1 || is the “worst manmade epidemic in history.”⁵ Twenty years ago, this problem did
2 || not exist; it was created by companies to turn a profit.

3 1.10 This public lawsuit is brought because Defendants repeatedly filled
4 enormous orders of opioids without reporting those orders as “suspicious orders”
5 in violation of federal and Washington State law, thereby playing an integral role
6 in perhaps the largest influx of drugs in American history.

7 1.11 This public lawsuit is unique because of the addictiveness of
8 opioids. Patients quickly became dependent on opioids and, once hooked, were
9 susceptible to a host of foreseeable adverse consequences, including addiction
10 and death. Defendants knew of, and profited from, the addictive properties of the
11 drugs they distributed.

12 1.12 Distributors operate under specific obligations as part of a
13 comprehensive scheme in place to prevent distributors from inadvertently
14 supplying prescription medication that is diverted from legitimate prescribed use.

15 1.13 The Attorney General, on behalf of the State of Washington, asks
16 this Court to enjoin the Defendants unfair distributions practices related to
17 opioids. The Attorney General further asks this Court to order the Defendants to
18 abate the public nuisance created by their business practices, to disgorge profits

⁵ Gary Franklin et al., *A Comprehensive Approach to Address the Prescription Opioid Epidemic in Washington State: Milestones and Lessons Learned*, 105(3): 463-469, American Journal of Public Health (Mar. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4330848/>, hereafter as Franklin, *A Comprehensive Approach*.

1 gained by their business practices, to impose penalties for illegal conduct, and to
2 award damages.

3 1.14 Having played a significant part in creating this crisis and profiting
4 to the tune of billions of dollars, Distributor Defendants are responsible for the
5 costs of their conduct that are now being borne by the public.
6

II. PARTIES

7 2.1 The Plaintiff is the State of Washington. The Attorney General is
8 authorized to commence this action pursuant to RCW 19.86.080 and RCW
9 19.86.140. The State, by and through the Attorney General and the Consumer
10 Protection Division, brings this action to address practices that violate the
11 Consumer Protection Act relating to the distribution of opioid medications. The
12 Attorney General is also authorized to bring this action pursuant to its common
13 law and *parens patriae* authority to bring an action to abate a public nuisance and
14 vindicate the rights of the public.

15 2.2 Defendant McKesson Corporation (“McKesson”) is a corporation
16 organized under the laws of the State of Delaware with its principal place of
17 business in San Francisco, California. During all relevant times, McKesson has
18 distributed substantial amounts of prescription opioids to providers and retailers
19 in Washington.

20 2.3 Defendant Cardinal Health, Inc. (“Cardinal”) is a corporation
21 organized under the laws of the State of Ohio with its principal place of business
22 in Dublin, Ohio. During all relevant times, Cardinal has distributed substantial
amounts of prescription opioids to providers and retailers in Washington.

1 2.4 Defendant AmerisourceBergen Corporation (“AmerisourceBergen”)
2 is a corporation organized under the laws of the State of Delaware with its
3 principal place of business in Chesterbrook, Pennsylvania. During all relevant
4 times, AmerisourceBergen has distributed substantial amounts of prescription
5 opioids to providers and retailers in Washington.

6 2.5 Defendants are in the business of distributing opioids in the United
7 States and Washington. The opioids Defendants distribute include, but are not
necessarily limited to, the following:

- 8 a. Oxycodone;
- 9 b. Hydrocodone;
- 10 c. Fentanyl;
- 11 d. Codeine;
- 12 e. Morphine;
- 13 f. Hydromorphone;
- 14 g. Oxymorphone;
- 15 h. Tapentadol;
- 16 i. Meperidine;
- 17 j. Opium;
- 18 k. Levorphanol; and
- 19 l. Methadone.

20 2.6 As discussed further below, each of the Defendants has consistently
21 failed to comply with its legal obligations concerning suspicious order reporting
and opioid diversion. In fact, each has been subject to remedial action by the
22

1 Drug Enforcement Agency to resolve government allegations regarding the
2 failure to monitor and prevent diversion of dangerous and addictive opioids.

3

III. JURISDICTION AND VENUE

4 3.1 The State files this complaint and institutes these proceedings under
5 the provisions of the Consumer Protection Act, RCW 19.86; the State also brings
6 this action in its *parens patriae* capacity for the benefit of the state's residents, to
7 protect their health and safety.

8 3.2 The Defendants have engaged in the conduct set forth in this
9 Complaint in King County and elsewhere in the state of Washington. Personal
10 jurisdiction is therefore appropriate under RCW 19.86.160.

11 3.3 Venue is proper in King County pursuant to RCW 4.12.020 and
12 4.12.025, and Superior Court Civil Rule because the Defendants transact business
13 in King County by marketing and distributing the opioid products to health care
14 providers and pharmacies in King County, as described more fully below.

15

IV. FACTS

16 4.1 Opioids are powerful analgesic medications intended for the
17 treatment of acute pain. Defendants distribute prescription opioids, which are
18 intended for the treatment of pain, to retailers and pharmacies.

19 4.2 Although the Food and Drug Administration has approved the sale
20 of opioids, and the Drug Enforcement Administration permits their distribution
21 by licensed distributors, Defendants' distribution of these drugs was contrary to
22 the DEA requirements, and does not shield Defendants from liability for their

1 unfair and negligent conduct, or the public nuisance created by their business
2 model.

3 4.3 Washington State has a strong public policy in favor of protecting its
4 citizens, which extends to preventing Defendants' unfair and negligent
5 distribution of opioids and abating the public nuisance created by the widespread
6 distribution of opioids.

7 4.4 In contravention of Washington's public policy, Defendants
8 distributed opioids in massive, patently unsafe quantities throughout Washington,
9 without taking adequate steps to prevent diversion, to refuse orders, or to even
10 report suspicious orders. Defendants acted despite the massive and sustained
11 public harms that were or should have been known to them.

12 4.5 Over the past 20 years, the use of opioids – both legal and illegal –
13 has exploded. The primary change in treating pain in the United States over the
14 last two decades has been the increased prescription of opioids, despite the risk of
15 opioid abuse. In the last 20 years, opioid prescribing has increased by 600
percent.⁶

16 4.6 In fact, the primary change in treating pain in the United States over
17 the last two decades has been the increased prescription of opioids, even though
18 there has not been a commensurate increase in pain treatments. By way of

19 6 Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of*
20 *Pain Medications* (2014), citing Leonard Paulozzi et al., *CDC Grand Rounds Prescription*
21 *Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012),
22 *available at*
<https://www.colorado.gov/pacific/sites/default/files/Psychological%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf>.

1 example, in 2010, almost 20 percent of visits to the doctor for pain relief resulted
2 in an opioid prescription.⁷ This represented a 73 percent increase in visits
3 resulting in an opioid prescription from 2000. Over that same period, non-opioid
4 pain treatments remained relatively constant.⁸

5 4.7 At its peak in 2012, U.S. health care providers wrote 259 million
6 prescriptions for opioid pain medication, enough for every adult in the United
7 States to have a bottle of pills.⁹ Although that number has declined somewhat in
8 recent years, in 2017, health care providers still wrote over 191 million
9 prescriptions, amounting to more than one prescription for every two people in
10 the United States.¹⁰ The United States constitutes 4.6 percent of the world's
population, but consumed 80% of the world's opioid supply in 2011.¹¹

11 4.8 Washington has 0.1% of the world's population, but in 2016
12 consumed 1.8% of the world's opioids.¹² This means Washington consumes
13 nearly 20 times the opioids its population would suggest.

14 7 Matthew Daubresse et al., *Ambulatory Diagnosis and Treatment of Non-Malignant*
15 *Pain in the United States, 2000-2010*, 51(10): 10.1097, Med Care (Oct. 2013) available at
16 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3845222/>.

17 8 *Id.*

18 9 Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for*
19 *Prescribing Opioids for Chronic Pain – United States, 2016*, 65(1) Morbidity and Mortality
20 Weekly Report (Mar. 2016), available at
21 <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>, hereafter as Dowell, *CDC*
22 *Guideline for Prescribing*.

23 10 U.S. Opioid Prescribing Rate Maps (Oct. 3, 2018) available at
24 <https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html>.

25 11 Teater, *supra*, citing Daneshvari R. Solanki et al., *Monitoring Opioid Adherence in*
26 *Chronic Pain Patients: Assessment of Risk of Substance Abuse*, 14 Pain Physician Journal
27 (Apr. 2011), available at
28 <https://www.painphysicianjournal.com/current/pdf?article=MTQ0NQ%3D%3D&journal=60>.

29 12 U.S. and World Population Clock, U.S. Census Bureau (Mar. 1, 2019, 2:54 PM),
30 <https://www.census.gov/popclock/>.

1 4.9 As set forth below, the risks associated with opioid use were well-
2 known in the industry, and the widespread addiction and epidemic creation
3 should have been known or was known by the Defendants.

4 4.10 The result of Defendants' unfair and negligent conduct dramatically
5 impacted Washington State and has caused extensive public harm.

6 **A. Opioids Are Massively Dangerous.**

7 4.11 Opioids are a class of central nervous system depressant drugs that
8 attach to receptors in the brain, spinal cord, and gastrointestinal tract and
9 suppresses function. There are several different opioid molecules – morphine,
10 hydrocodone, oxycodone, oxymorphone, hydromorphone, tapentadol
buprenorphine, and methadone being the most common.

11 4.12 Prescribed for pain relief, opioids also depress respiration, which is
12 the primary mechanism by which opioids have killed thousands of Washington
13 citizens and hundreds of thousands of Americans. It is undisputed that opioids are
14 both addictive and deadly.

15 4.13 Prescription opioids constitute the largest component of the opioid
16 epidemic, both in quantity and damage caused.¹³ Overdose deaths parallel the
17

18 ¹³ More than half of all opioid deaths in Washington involve prescription opioids, and,
19 nationwide, from 1999 to 2015, 183,000 deaths involved prescription opioids. U.S. Department
20 of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019) available at
21 <https://www.hhs.gov/opioids/about-the-epidemic/index.html>; Rose A. Rudd et al., *Increases in
Drug and Opioid-Involved Overdose Deaths – United States, 2010-2015*, 65(50-51) Morbidity
and Mortality Weekly Report (Dec. 2016) available at
22 <https://www.cdc.gov/mmwr/volumes/65/wr/mm655051e1.htm>, hereafter as Rudd, *Increases
2010-2015*.

1 prescribing of opioids.¹⁴ In fact, filling an opioid prescription is a significant risk
2 factor for overdose.¹⁵

3 4.14 Both opioid use disorder and overdose risk are present even when
4 opioids are taken as prescribed.¹⁶

5 4.15 Opioids are massively dangerous. Between 1999 and 2014, more
6 than 165,000 Americans died of opioid overdose.¹⁷ Deaths related to opioids are
7 accelerating. In 2011, the Center for Disease Control and Prevention declared
8 that prescription opioid deaths had reached “epidemic levels.”¹⁸ That year,
9 11,693 people died of prescription opioid overdoses.¹⁹ Since then, prescription
10 opioid deaths have *more than quadrupled*, reaching 47,600 Americans in 2017—
11 more than ten times the number of Americans who have died in the entire Iraq
12 War.²⁰

13 ¹⁴ Rose A. Rudd et al., *Increases in Drug and Opioid Overdose Deaths – United States,*
14 *2000-2014*, 64(50):1378-82, Morbidity and Mortality Weekly Report (Jan. 2016), available at
15 <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6450a3.htm>.

16 ¹⁵ Dowell, *supra* note 9, at 22-24.

17 ¹⁶ Letter from Janet Woodcock, MD., Dir., Center for Drug Eval. and Research, to
18 Andrew Kolodny, M.D. (Sept. 10, 2013), available at https://www.supportprop.org/wp-content/uploads/2014/12/FDA_CDER_Response_to_Physicians_for_Responsibile_Opioid_Prescribing_Partial_Petition_Approval_and_Denial.pdf, hereafter as Woodcock Letter (Sept. 10, 2013).

19 ¹⁷ Dowell, *CDC Guideline for Prescribing* at 2.

20 ¹⁸ Press Release, Centers for Disease Control and Prevention: *Prescription Painkiller Overdoses at Epidemic Levels* (Nov. 1, 2011), available at https://www.cdc.gov/media/releases/2011/p1101_flu_pain_killer_overdose.html.

21 ¹⁹ Li Hui Chen, M.S., Ph.D.; Holly Hedegaard, M.D., M.S.P.H.; and Margaret Warner, Ph.D., *Drug-poisoning Deaths Involving Opioid Analgesics: United States, 1999–2011*, 166 NCHS Data Brief (Sept. 2014) available at <https://www.cdc.gov/nchs/data/databriefs/db166.pdf>.

22 ²⁰ U.S. Department of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019) available at <https://www.hhs.gov/opioids/about-the-epidemic/index.html>; German Lopez, *2017 was the worst year ever for drug overdose deaths in America* (Aug. 16, 2018)

1 4.16 Dr. Thomas Frieden from the CDC explained, “[w]e know of no
2 other medication routinely used for a nonfatal condition that kills patients so
3 frequently.”²¹

4 4.17 Aside from overdose, long-term opioid use is associated with a
5 significant increase in mortality from other causes.²²

6 4.18 Opioids are also associated with numerous other side effects
7 including gastrointestinal impacts, delayed recovery from injury, cognitive
8 impacts, endocrine impacts, hyperalgesia (increased sensitivity to pain),
9 increased risks of fractures, gastrointestinal bleeding, hospitalization among the
10 elderly, tolerance (need for increasing dose to maintain effect), dependence
11 (causing withdrawal if stopped), and addiction.²³

12 4.19 Opioids carry special risks for certain vulnerable populations. For
13 example, opioid use during pregnancy has seen a three to- to four-fold increase
14 between 2000 and 2009, with increased fetal, obstetrical, and neonatal abstinence
15 syndrome risk. Neonatal abstinence syndrome may occur in up to 60-80 percent

16 available at <https://www.vox.com/science-and-health/2018/8/16/17698204/opioid-epidemic-overdose-deaths-2017>.

17 ²¹ Thomas R. Frieden & Debra Houry, *Reducing the Risks of Relief – The CDC Opioid-Prescribing Guideline*, 374:1501-1504, New England Journal of Medicine (Apr. 2016), available at <https://www.nejm.org/doi/full/10.1056/NEJMp1515917>.

18 ²² Wayne A. Ray et al., *Prescription of Long-Acting Opioids and Mortality in Patients With Chronic Noncancer Pain*, 315(22):2415-2423, Journal of the American Medical Association (Jun. 2016), available at <https://jamanetwork.com/journals/jama/fullarticle/2528212>.

19 ²³ Donald Teater, Nat'l Safety Council, *The Psychological and Physical Side Effects of Pain Medications* (2014), citing Leonard Paulozzi et al., *CDC Grand Rounds Prescription Drug Overdoses – a U.S. Epidemic*, 61 Morbidity and Mortality Weekly Report 10 (2012), available at <https://www.colorado.gov/pacific/sites/default/files/Psychological%20and%20Physical%20Side%20Effects%20Teater%20NSC.pdf>.

1 of infants exposed to opioids and has increased every year through 2013.²⁴ Of
2 pregnant women enrolled in Medicaid from 2000 to 2007, 21.6% filled an opioid
3 prescription during pregnancy.²⁵

4 4.20 Opioids also pose risks for children and adolescents. Most of the use
5 in this population is off-label as opioids are not approved for children. Use of
6 prescription opioid pain medication before high school graduation is associated
7 with a 33% increase in the risk of later opioid misuse. The misuse of opioids in
8 adolescents strongly predicts the later onset of heroin use.²⁶ Nonetheless, the
9 2016 CDC guidelines found that there have been significant increases in opioid
10 prescribing for children and adolescents, for conditions such as headaches and
sports injuries.

11 4.21 Opioids also pose special risks for older patients as well, in part due
12 to the decline in the ability to metabolize and excrete opioids. Older patients on
13 opioids are particularly prone to constipation, have increased risk for falls and
14 fractures, and have a higher risk of opioid-related adverse drug events.²⁷

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24 Washington State Agency Medical Director's Group (WSAMDG), *Interagency Guideline on Prescribing Opioids for Pain*, 3rd ed. (Jun. 2015), available at <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpioidGuideline.pdf>, hereafter as WSAMDG, *Interagency Guideline*.

25 *Id.* at 43.

26 Deborah Dowell, Tamara M. Haegerich & Roger Chou, *CDC Guideline for Prescribing Opioids for Chronic Pain – United States*, 2016, 65(1) Morbidity and Mortality Weekly Report (Mar. 2016), available at <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1.pdf>, hereafter as Dowell, *CDC Guideline*.

27

WSAMDG, *Interagency Guideline* at 47-48.

1 || B. Opioids Are Highly Addictive.

2 4.22 Opioids are also extremely addictive. Studies have found diagnosed
3 opioid dependence rates in primary care settings as high as 26%.²⁸ Among opioid
4 users who received four prescriptions in a year, 41.3% meet diagnostic criteria
5 for a lifetime opioid-use disorder.²⁹

4.23 Once a patient starts opioid treatment, it is extraordinarily difficult
6 to stop. A 2017 CDC study determined that the probability of long-term use
7 escalates most sharply after five days, and surges again when one month of
8 opioids are prescribed.³⁰ A patient initially prescribed one month of opioids has a
9 29.9 percent chance of still using at one year.³¹ In one study, almost 60 percent of
10 patients who used opioids for 90 days were still using opioids five years later.³²

4.24 The difficulty in stopping use is particularly true for patients first
prescribed an extended release opioid. Patients who initiated treatment on an
extended release opioid – such as OxyContin – have a 27.3 percent likelihood to

²⁸ Dowell, *CDC Guideline*.

²⁹ Joseph A. Boscarino, Stuart N. Hoffman & John J. Han, *Opioid-Use Disorder Among Patients on Long-Term Opioid Therapy: Impact of Final DSM-5 Diagnostic Criteria on Prevalence and Correlates*, 6:83-91, Substance Abuse and Rehabilitation (Aug. 2015), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4548725/>. See also Joseph A. Boscarino et al., *Prevalence of Prescription Opioid-Use Disorder Among Chronic Pain Patients: Comparison of the DSM-5 vs. DSM-4 Diagnostic Criteria*, 30(3):185-94, Journal of Addictive Diseases (Sept. 2011), (showing a 34.9% lifetime opioid use disorder) available at <https://www.ncbi.nlm.nih.gov/pubmed/21745041>.

³⁰ Anuj Shah, Corey J. Hayes & Bradley C. Martin, *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use – United States, 2006-2015*, 66(10):265-269, Morbidity and Mortality Weekly Report (Mar. 2017), available at <https://www.cdc.gov/mmwr/volumes/66/wr/mm6610a1.htm>, hereafter as Shah, *Characteristics of Initial Prescription*.

31 *Id.*

³² Bradley C. Martin et al., *Long-Term Chronic Opioid Therapy Discontinuation Rates from the TROUP Study*, 26(12):1450-1457, Journal of General Internal Medicine (Jul. 2011), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3235603/>.

1 || be using opioids one year later, and a 20.5 percent likelihood of using opioids
2 || three years later.³³

3 4.25 In requiring a new black-box warning on the labels of all immediate
4 release opioids in March 2013, the FDA noted the “known serious risk[] of . . .
5 addiction” which was present “even at recommended doses of all opioids.”³⁴

6 4.26 The CDC found that “[o]pioid pain medication use presents serious
7 risks, including overdose and opioid use disorder” – a technical term for
8 addiction.³⁵ The CDC emphasized that “continuing opioid therapy for 3 months
substantially increases risk for opioid use disorder.”³⁶

9 4.27 Whether in the end a patient meets the clinical definition of
10 addiction or is simply dependent and unable to stop using opioids, once opioids
11 are prescribed for even a short period of time, patients are hooked.

12 4.28 Distributing a substance as dangerous and addictive as opioids
13 quickly crosses the line into an unfair trade practice.

14 4.29 Because opioids cause tolerance and dependence, patients who take
15 the drugs for even a short time become a physiologically captured market.

16 4.30 According to the U.S. Department of Health and Human Services,
17 more than two million Americans are opioid-dependent.³⁷

³³ Shah, *Characteristics of Initial Prescription.*

³⁴ Woodcock Letter (Sept 10, 2013).

³⁵ Dowell, *CDC Guideline for Prescribing*, at 2.

³⁶ Dowell, *CDC Guideline for Prescribing*, at 21.

³⁷ U.S. Department of Health and Human Services, *What is the U.S. Opioid Epidemic?* (Jan. 2019) available at <https://www.hhs.gov/opioids/about-the-epidemic/index.html>.

4.31 Use of prescription opioids often enters injured people into a cycle of addiction, with prescription opioid use leading directly to heroin addiction. One study found that approximately 75 to 80% of those who started using heroin in recent years began with prescription opioids.³⁸ A CDC study concluded that prescription opioid use is the single greatest risk factor for heroin use.³⁹

4.32 Through this cycle of addiction, the massive proliferation in prescription opioids throughout the United States and Washington has also led directly to a surge in the use of illegal opioids, including heroin and illicit fentanyl. Rates of heroin addiction have increased 286 percent since 2002.⁴⁰ And since 1999, heroin overdose deaths have increased seven-fold,⁴¹ reaching over 15,000 in 2017.⁴²

C. Federal and State Requirements for the Prevention of Drug Diversion.

4.33 Both federal and state law recognize the addiction risks associated with prescription opioids. Indeed, most prescription opioids are classified as Schedule II controlled substances, meaning they have a “high potential for abuse” that “may lead to severe psychological or physical dependence.” 21 U.S.C. § 812(b)(2); RCW 69.50.205.

³⁸ Theodore J. Cicero, *The Changing Face of Heroin Use in the United States: A retrospective analysis of the past 50 years*, 71(7):821-826, JAMA Psychiatry (Jul. 2014), available at <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.

³⁹ Centers for Disease Control and Prevention, *Today's Heroin Epidemic* (Jul. 2015), available at <https://www.cdc.gov/vitalsigns/heroin/index.html>.

⁴⁰ Centers for Disease Control and Prevention, *Today's Heroin Epidemic Infographics* (Jul. 2015), available at <https://www.cdc.gov/vitalsigns/heroin/infographic.html>.

⁴¹ Centers for Disease Control and Prevention, *Drug Overdose Deaths in the United States, 1999-2017* (Nov. 2018), available at <https://www.cdc.gov/nchs/products/databriefs/db329.htm>.

⁴² Centers for Disease Control and Prevention, *Heroin Overdose Data* (Dec. 2018) available at <https://www.cdc.gov/drugoverdose/data/heroin.html>.

1 4.34 As distributors, Defendants play an important role in preventing
2 diversion. Once prescription opioids are manufactured and packaged, they are
3 transferred to Defendants and other distributors. Defendants can then supply
4 these prescription opioids to healthcare providers, such as pharmacies and
5 hospitals, which then dispense the drugs to end users.

6 4.35 To ensure that the goal of ensuring that prescription opioids are not
7 diverted from their intended and legal channels, Distributors are subject to a
8 number of specific duties under federal and state law to prevent the diversion of
9 opioids for illicit use.

10 4.36 At the distributor level, the principle risk of diversion comes
11 whenever opioid distributors fill suspicious orders from retailers. Suspicious
12 orders include unusually large orders, orders that are disproportionately large in
13 comparison to the population of a community served by a pharmacy, unusually
14 frequent orders, and orders that deviate from a particular customer's normal
15 patterns. Diversion can also occur when distributors allow opioids to be lost or
16 stolen in transit.⁴³

17 4.37 As registered distributors, each Defendant has a duty to comply with
18 all of the requirements imposed by the CSA and Washington law and the
19 regulations adopted under each.

20 43 “This closed-system is specifically designed to ensure that there are multiple
21 ways of identifying and preventing diversion through active participation by registrants
22 within the drug delivery chain as well as the registrants within the health care delivery
system.” Statement of Joseph T. Rannazzisi, Deputy Assistant Administrator, Drug
Enforce Administration, before the Caucus on International Narcotics Control, United
States Senate (Jul. 18, 2012), *available at*
<https://www.dea.gov/sites/default/files/pr/speeches-testimony/2012-2009/responding-to-prescription-drug-abuse.PDF>.

1 4.38 Each Defendant also has a common-law duty to exercise reasonable
2 care under the circumstances not to create a foreseeable risk of harm to others
3 stemming from their distribution of dangerous drugs.

4 4.39 Under the CSA and Washington law,⁴⁴ Defendants must “provide
5 effective controls and procedures to guard against theft and diversion of
6 controlled substances,” including opioids. 21 C.F.R. § 1301.71(a); *see also* 21
7 U.S.C. § 823(b)(1) (requiring distributors to provide “effective control against
8 diversion of particular controlled substances into other than legitimate medical,
9 scientific, and industrial channels.”); WAC 246-879-080 (“Wholesale drug
10 distributors that deal in controlled substances . . . shall comply with applicable
11 state, local, and DEA regulations.”); WAC 246-879-050(7) (“All applicants for a
12 license as a controlled substances wholesaler must comply with the security
13 requirements as found in” DEA regulations, including 21 C.F.R. § 1301.71.)
14 RCW 69.50.303, 304 (providing for suspension or revocation of licenses for any
15 distributors who, among other things, fail to maintain “effective controls against
16 diversion of controlled substances into other than legitimate medical, scientific,
research, or industrial channels”).

17 4.40 To that end, Defendants must “design and operate a system” that
monitors and reports “suspicious orders” to the DEA. 21 C.F.R. § 1301.74(b); *see*
18 *also* WAC 246-879-050(7) (“All applicants for a license as a controlled
19

20 ⁴⁴ Distributors of controlled substances in Washington are required to register with
both the DEA and the Washington Department of Health. 21 C.F.R. § 1301.11; RCW
21 18.64.046; RCW 69.50.302. The requirements of the CSA have been explicitly adopted
and incorporated into Washington law. WAC 246-879-080; RCW 69.50.306; WAC 246-
22 887-020 (“[T]he federal regulations are specifically made applicable to registrants in this
state[.]”).

1 substances wholesaler must comply with the security requirements as found in 21
2 C.F.R. . . . 1301.74[.]").

3 4.41 "Suspicious orders" are orders of "unusual size, orders deviating
4 substantially from a normal pattern, and orders of unusual frequency." *Id.*

5 4.42 Defendants are not allowed to ship any suspicious orders unless they
6 conclude that the order is not likely to be diverted. That order must nonetheless
7 be reported to the DEA, even if it cleared for shipment. 21 C.F.R. § 1301.74(b);
8 *see also* Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator,
9 Office of Diversion Control, DEA, to Cardinal Health (Sept. 27, 2006), filed in
10 *Cardinal Health Inc. v. Holder*, No. l:12-cv-00185-RBW, 846 F.Supp.2d 203
11 (D.D.C. Feb. 10, 2012), Dkt. ##14-51, attached hereto as **Exhibit A** at 3 (The
12 "reporting requirement is in addition to, and not in lieu of, the general
13 requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls
against diversion.").⁴⁵

14 4.43 Washington law similarly requires each distributor to maintain a
15 complete and accurate record of each substance manufactured, sold, delivered,
16 lost, stolen, or otherwise disposed of. WAC 246-879-040; RCW 69.50.306;
17 WAC 246-887-020.

18 **D. Defendants' Are Aware of their Regulatory Obligations.**

19 4.44 These legal requirements are known to Defendants. Throughout the
20 relevant time period, Defendants had access to and received specific guidance

21 45 In addition, Distributors must report all shipments of controlled substances to the
22 DEA by and through the Automation of Reports and Consolidated Orders System (ARCOS).
21 U.S.C. § 827(d)(l); 21 C.F.R. §§ 1304.33(d),(e).

1 from the DEA regarding their obligations to stop diversion through effective
2 monitoring of suspicious orders.

3 4.45 These include, but are not limited to, online guidance and in person
4 conferences. Defendants have attended at least one of the conferences.⁴⁶

5 4.46 In addition, the Defendants received at least two letters providing
6 guidance for meeting their statutory monitoring and reporting obligations under
federal, and by extension, state law.

7 4.47 Amongst other things, the letters “reiterated” Defendants’ diversion
8 monitoring responsibilities in light of “the prescription drug abuse problem our
9 nation currently faces,” and its “substantial and detrimental effect on the health
10 and general welfare of the American people.”⁴⁷

11 4.48 The DEA clarified distributors are not absolved of responsibility by
12 “merely. . . filing a suspicious order report”; in order to be fully compliant,
13 distributors must “conduct an independent analysis of suspicious orders prior to
14 completing a sale.”⁴⁸ The DEA cautioned that distributors who “rely on rigid

16 46 Distributor Conferences (2013-2016) *available at*
17 <https://www.deadiversion.usdoj.gov/mtgs/distributor/index.html>; Manufacturer Conferences
18 (2013-2015) *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/index.html; National Conference on Pharmaceutical and Chemical Diversion (2008-2017) *available at*
19 https://www.deadiversion.usdoj.gov/mtgs/drug_chemical/index.html; Diversion Awareness
Conferences (2011-2017) *available at*
20 https://www.deadiversion.usdoj.gov/mtgs/pharm_awareness/index.html.

21 47 Exhibit A (citing 21 U.S.C. § 801(2)).

22 48 Letter from Joseph T. Rannazzisi, Deputy Assistant Administrator, Office of
Diversion Control, DEA, to Cardinal Health (Dec. 27, 2007), filed in *Cardinal Health Inc. v. Holder*, No. 1:12-cv-00185-RBW, 846 F.Supp.2d 203 (D.D.C. Feb. 10, 2012), Dkt. ##14-8,
attached hereto as **Exhibit B**.

1 formulas to define whether an order is suspicious may be failing to detect
2 suspicious orders.”⁴⁹

3 4.49 In particular, the DEA explained that suspicious-order factors
4 identified in the regulation – “orders of unusual size, order deviating substantially
5 from a normal pattern, and orders of an unusual frequency” – were to be broadly
6 construed as necessary to achieve the regulatory goal of preventing diversion of
7 dangerous drugs.⁵⁰ The DEA explained that “[t]he determination of whether an
8 order is suspicious depends not only on the ordering patterns of the particular
9 customer, but also on the patterns of the registrant's customer base and the
10 particular patterns throughout the segment of the regulated industry.”⁵¹

11 4.50 As the DEA explained:

12 For example, a system that identifies orders as suspicious only
13 if the total amount of a controlled substance ordered during one
14 month exceeds the amount ordered the previous month by a certain
15 percentage or more is insufficient. This system fails to identify
16 orders placed by a pharmacy if the pharmacy placed unusually large
17 orders from the beginning of its relationship with the distributor.
18 Also, this system would not identify orders as suspicious if the order
19 were solely for one highly abused controlled substance if the orders
20 never grew substantially. Nevertheless, ordering one highly abused
21 controlled substance and little or nothing else deviates from the
22 normal pattern of what pharmacies generally order.⁵²

20 49 *Id.*
21 50 *Id.*
22 51 *Id.*
23 52 *Id.*

1 4.52 The DEA also included pragmatic and immediately applicable
2 resources, including a questionnaire for pharmacies to identify legitimate
3 orders.⁵³

4 4.53 In short, for well over a decade, the DEA has repeatedly affirmed
5 that distributors' legal obligation to maintain "effective control against diversion
6 of particular controlled substances," 21 U.S.C. § 823(b)(l), is not merely a box to
7 be checked. Instead, to comply with their legal obligations, distributors' anti-
8 diversion efforts must be active, they must be flexible, and they must be
effective.

9 4.54 In addition to DEA guidance, Defendants' own industry group, the
10 Healthcare Distribution Management Association (HDMA), published
11 compliance guidelines emphasizing distributors' obligations to actively monitor
12 and prevent suspicious orders. Those guidelines, entitled "Reporting Suspicious
13 Orders and Preventing Diversion of Controlled Substances," stressed that
14 distributors were "[a]t the center of a sophisticated supply chain," and thus
15 "uniquely situated to perform due diligence in order to help support the security
16 of controlled substances they deliver to their customers."⁵⁴ The guidelines set
17 forth detailed steps distributors should follow to conduct due diligence regarding
18 their customers and to identify and investigate suspicious orders.⁵⁵ And,
consistent with DEA guidance, the guidelines explain that when a distributor

53 Exhibit A.

⁵⁴ Healthcare Distribution Management Association (HDMA), *Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances*, attached hereto as **Exhibit C**.

55 *Id.*

1 identifies an order “as an order of interest, the distributor should not ship to the
2 customer . . . any units of the specific drug code product as to which the order
3 met or exceeded a threshold or as to which the order was otherwise characterized
4 as an order of interest.”⁵⁶

4.55 Opioid distributors recognize the magnitude of the problem and have made statements assuring the public they recognize their duty to curb the opioid epidemic.⁵⁷

4.56 One of Cardinal’s executives recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”⁵⁸

4.57 McKesson has publicly stated that it has a “best-in-class controlled substance monitoring program to help identify suspicious orders” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”⁵⁹

4.58 AmerisourceBergen publicly claims that it ensures safe and secure drug distribution by, among other things, “continuously evaluat[ing], enhanc[ing] strengthen[ing] and expand[ing] the proven measures [they] have implemented to maintain the integrity of every order [they] ship.” Indeed, it states that its “role in

⁵⁶ *Id.* at 9 (emphasis in original).

⁵⁷ Lenny Bernstein et al., *How Drugs Intended for Patients Ended up in the Hands of Illegal Users: 'No one was doing their job'*, The Denver Post (Oct. 22, 2016), available at <https://www.denverpost.com/2016/10/23/drugs-intended-for-patients-illegal-users/>.

58 *Id*

⁵⁹ Scott Higham et al., *Drug Industry Hired Dozens of Officials from the DEA as the Agency Tried to Curb Opioid Abuse*, The Washington Post (Dec. 22, 2016), available at <http://wapo.st/2uR2FDy>.

1 the healthcare supply chain uniquely positions [them] to contribute important
2 expertise and resources to the battle against opioid abuse in the United States.”⁶⁰

3 4.59 Defendants have publicly recognized their role in curbing criminal
4 opioid activity, and claim that they are expeditiously and continuously
5 implementing tools to curb the opioid epidemic. Distributor Defendants have a
6 duty to act reasonably by following through on their assurances.

7 **E. Defendants Have Each Been Sanctioned for their Failure to Maintain
8 Effective Anti-Diversion Controls.**

9 4.60 The Defendants are or should be fully aware of their obligations to
10 maintain effective controls to prevent the diversion of highly dangerous and
11 addictive prescription opioids. And yet, going back well over a decade, each of
12 the Defendants has illegally, recklessly, and/or negligently flooded the United
13 States and Washington with opioid pills without maintaining effective
14 antidiversion controls. As a result, the Defendants have been subject to
enforcement actions by the DEA and other federal and state agencies.

15 **1. McKesson**

16 4.61 McKesson has twice been subject to civil penalties from the DEA
17 due to its failure to maintain effective antidiversion controls.

18 4.62 McKesson first entered into a settlement agreement with the DEA in
19 May 2008, when it agreed to pay \$13.25 million to settle claims that it failed to
20 maintain effective controls to prevent diversion of opioids across six states.⁶¹

21 ⁶⁰ <https://www.amerisourcebergen.com/abcnew/fighting-the-opioid-epidemic>.

22 ⁶¹ U.S. Dep’t of Justice, *McKesson Corporation Agrees to Pay More than \$13 Million to Settle Claims that it Failed to Report Suspicious Sales of Prescription*

4.63 In that case, the government alleged that “McKesson distribution centers received and filled hundreds of suspicious orders placed by pharmacies participating in illicit Internet schemes, but failed to report the orders to DEA.”⁶² Moreover, McKesson allegedly engaged in this illegal conduct “even after a Sept.1, 2005, meeting at which DEA officials met with and warned McKesson officials about excessive sales of their products to pharmacies filling illegal online prescriptions.”⁶³ “As a result, millions of dosage units of controlled substances were diverted from legitimate channels of distribution.”⁶⁴

4.64 As part of the 2008 agreement, “McKesson developed a Controlled Substance Monitoring Program (“CSMP”) in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA.”⁶⁵ Specifically, McKesson agreed to “maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP.”⁶⁶

4.65 Despite its statutory, regulatory, and now contractual obligations, McKesson comprehensively failed to implement an effective antidiversion program following the 2008 settlement agreement.

Medications, (May 2008) available at <https://www.justice.gov/archive/opa/pr/2008/May/08-opa-374.html>.

62 *Id.*

63 *Id.*

64 Id.

⁶⁵ January 2017 Settlement Agreement and Release, attached hereto as **Exhibit D**, at ¶ III.B (discussing 2008 settlement agreement) dated January 5, 2017.

⁶⁶ *Id.* at § I. General at 3.

1 4.66 Thus, in 2017, McKesson again agreed to pay a civil penalty for its
2 failure to maintain effective diversion controls—this time for a record \$150
3 million.⁶⁷

4 4.67 The conduct underlying the 2017 settlement agreement covered 14
5 states, including Washington.⁶⁸

6 4.68 The evidence following the government’s investigation showed that
7 McKesson failed to maintain effective antidiversion controls, despite its 2008
8 settlement agreement. Indeed, as just one example, the DEA found that between
9 June 2008 and May 2013, one McKesson distribution facility “processed more
10 than 1.6 million orders for controlled substances . . . , but reported just 16 orders
11 as suspicious, all connected to one instance related to a recently terminated
customer.”⁶⁹

12 4.69 As part of the 2017 settlement agreement, McKesson admitted to
13 and accepted responsibility for its failure to maintain effective antidiversion
14 controls.⁷⁰ Among other things, McKesson admitted that between January 1,
15 2009, and January 17, 2017, “it did not identify or report to DEA certain orders
16 placed by certain pharmacies which should have been detected by McKesson as
17 suspicious based on the guidance contained in the DEA Letters [discussed above]
18 about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C.

19 ⁶⁷ U.S. Dep’t of Justice, *McKesson Agrees to Pay Record \$150 Million Settlement for*
20 *Failure to Report Suspicious Orders of Pharmaceutical Drugs* (Jan. 17, 2017), available at
<https://www.justice.gov/opa/pr/mckesson-agrees-pay-record-150-million-settlement-failure-report-suspicious-orders>.

21 ⁶⁸ *Id.*

22 ⁶⁹ *Id.*

23 ⁷⁰ Exhibit D at ¶ IV.

1 || § 842(a)(5).”⁷¹ McKesson further admitted that, despite its 2008 settlement
2 agreement with the DEA, it had failed to “identify or report to DEA certain
3 orders placed by certain pharmacies, which should have been detected by
4 McKesson as suspicious, in a manner fully consistent with the requirements set
5 forth in the 2008” agreement.⁷²

6 4.70 In addition to a \$150 million civil penalty, McKesson agreed, as
7 part of its 2017 settlement agreement, to temporary suspension of its
8 registrations to distribute controlled substances from 12 distribution centers
nationwide, including multi-year suspensions in some cases.⁷³

9 **2. Cardinal**

10 4.71 Cardinal, for its part, has entered into at least five separate
11 settlement agreements in enforcement actions concerning its failure to maintain
12 antidiversion controls.

13 4.72 In 2008, shortly after McKesson’s first civil penalty, Cardinal paid
14 its own \$34 million penalty related to claims of opioid diversion from seven of its
15 warehouses around the United States, including one in Auburn, Washington.⁷⁴
The penalty stemmed from allegations that Cardinal fulfilled and failed to report
16 suspicious orders of hydrocodone associated with a “rogue Internet pharmacy.”⁷⁵

18 ⁷¹ *Id.* at ¶ IV.A.

19 ⁷² *Id.* at ¶ IV.B.

20 ⁷³ 2017 Administrative Memorandum of Agreement (Jan. 17, 2017), available at
21 <https://www.justice.gov/opa/press-release/file/928476/download>.

22 ⁷⁴ U.S. Attorney’s Office for the District of Colorado, *Cardinal Health Inc., Agrees To Pay \$34 Million To Settle Claims That It Failed To Report Suspicious Sales Of Widely-Abused Controlled Substances* (Oct. 2, 2008) available at
https://www.justice.gov/archive/usao/co/news/2008/October08/10_2_08.html.

22 ⁷⁵ *Id.*

1 According to the DEA, “Cardinal’s conduct allowed the ‘diversion’ of millions
2 of dosage units of hydrocodone from legitimate to non-legitimate channels.”⁷⁶

3 4.73 In announcing the 2008 settlement agreement, the DEA stated
4 that “[d]espite [its] repeated attempts to educate Cardinal Health on diversion
5 awareness and prevention, Cardinal engaged in a pattern of failing to report
6 blatantly suspicious orders for controlled substances filled by its distribution
7 facilities located throughout the United States.”⁷⁷

8 4.74 As part of its 2008 settlement agreement, “Cardinal agree[d] to
9 maintain a compliance program designed to detect and prevent diversion of
10 controlled substances as required under the CSA and applicable DEA
11 regulations.”⁷⁸ More specifically, Cardinal agreed to adopt procedures
12 through which “[o]rders that exceed established thresholds and criteria will
13 be reviewed by a Cardinal employee trained to detect suspicious orders for
14 the purposes of determining whether (i) such orders should be not filled and
15 reported to the DEA or (ii) based on a detailed review, the order is for a
16 legitimate purpose and the controlled substances are not likely to be diverted
17 into other than legitimate medical, scientific, or industrial channels.”⁷⁹

18 4.75 But despite its promises in the 2008 settlement agreement,
19 Cardinal reached another settlement agreement with the DEA in 2012
20 stemming from its failure to detect and prevent suspicious orders from a

21 ⁷⁶ *Id.*

22 ⁷⁷ *Id.*

23 ⁷⁸ 2008 Settlement Agreement, attached hereto as **Exhibit E**.

24 ⁷⁹ *Id.*

1 distribution center in Florida. In that case, the DEA alleged that in the three
2 years preceding the settlement, Cardinal shipped more than 12 million pills of
3 oxycodone to only four Florida pharmacies.⁸⁰

4 4.76 In that 2012 settlement agreement, Cardinal admitted that its due
5 diligence efforts and compliance with the 2008 settlement agreement were
6 inadequate.⁸¹ It agreed to strengthen its procedures for identifying and
7 reporting suspicious orders.⁸² The DEA imposed a two-year registration
8 suspension for the Florida distribution center from which the suspicious
9 shipments originated.⁸³

10 4.77 In 2016, Cardinal entered into two more settlement agreements
11 based on its violations of the CSA. In one, Cardinal agreed to \$34 million in
12 civil penalties based on its failure to report suspicious orders in Maryland and
13 Florida, and its failure to adhere to recordkeeping requirements in
14 Washington.⁸⁴ At the same time, Cardinal entered another settlement in

15 ⁸⁰ Drug Enforcement Agency, *DEA Suspends for Two Years Pharmaceutical*
16 *Wholesale Distributor's Ability to Sell Controlled Substances from Lakeland, Florida Facility*,
17 (May 15, 2012), available at
18 <https://web.archive.org/web/20151009061847/http://www.dea.gov/divisions/hq/2012/pr051512p.html>.

19 ⁸¹ 2012 Settlement Agreement, attached hereto as **Exhibit F**.

20 ⁸² *Id.*

21 ⁸³ *Id.*

22 ⁸⁴ U.S. Attorney's Office for the District of Maryland, *Settlement resolves multiple*
23 *investigations against Cardinal in Maryland, Florida, New York and Washington* (Dec. 23,
24 2016), available at <https://www.justice.gov/usao-md/pr/cardinal-health-agrees-44-million-settlement-alleged-violations-controlled-substances-act>; U.S. Attorney's Office for the Western
25 District of Washington, *United States Reaches \$34 Million Settlement with Cardinal Health for Civil Penalties under the Controlled Substances Act* (Dec. 23, 2016), available at
26 <https://www.justice.gov/usao-wdwa/pr/united-states-reaches-34-million-settlement-cardinal-health-civil-penalties-under-0>.

1 which it agreed to pay a \$10 million civil penalty to resolve allegations that
2 its subsidiary Kinray, Inc., failed to report suspicious orders in New York.⁸⁵

3 4.78 In January 2017, Cardinal paid the State of West Virginia \$20
4 million to settle allegations that it failed to report suspicious orders and
5 negligently flooded the state with prescription opioids, contributing to that
6 state’s opioid epidemic and contributing to over 1,700 overdose deaths.⁸⁶

7 **3. AmerisourceBergen**

8 4.79 In 2007, AmerisourceBergen lost its right to distribute controlled
9 substances from a distribution center amid allegations that it was not controlling
10 shipments of prescription opioids to internet pharmacies.⁸⁷ Over the course of
11 one year, AmerisourceBergen had distributed 3.8 million dosage units of
12 hydrocodone to “rogue pharmacies.”⁸⁸ The DEA suspended
13 AmerisourceBergen’s registration after determining that “the continued
14 registration of this company constitutes an imminent danger to public health and
15 safety.”⁸⁹

16
17 ⁸⁵ *Id.*

18 ⁸⁶ Ghose, Carrie, *Cardinal Health to pay West Virginia \$20M to settle opiates lawsuit*,
19 Columbus Business First (Jan. 9, 2017), available at
<https://www.bizjournals.com/columbus/news/2017/01/09/cardinal-health-to-pay-west-virginia-20m-to-settle.html>.

20 ⁸⁷ Drug Enforcement Agency, *DEA Suspends Orlando Branch of Drug Company from
21 Distributing Controlled Substances* (Apr. 24, 2007), available at
<https://www.dea.gov/sites/default/files/divisions/mia/2007/mia042407p.html>.

22 ⁸⁸ *Id.*

⁸⁹ *Id.*

4.80 Again in 2012, the DEA investigated AmerisourceBergen for failing to protect against diversion of particular controlled substances.⁹⁰

4.81 In 2017, Amerisource Bergen agreed to pay West Virginia \$16 million to settle a lawsuit concerning its role in fueling West Virginia's nation-worst opioid epidemic by negligently filling suspicious orders and failing to report them as required by law.⁹¹

F. Defendants Pumped Billions of Opioid Pills into Washington without Halting or Reporting Suspicious Orders.

4.82 Despite these multiple civil penalties, and their repeated acknowledgment that they are obligated to maintain effective controls to avoid diversion, Defendants have continuously filled and shipped orders that they knew or should have known were suspicious.

4.83 Defendants have also continuously failed to report orders they knew or should have known were suspicious.

4.84 Defendants owe duties under federal and state law to stop, investigate, and report orders of unusual size, orders deviating substantially from normal industry patterns, and unusually frequent orders. But Defendants have intentionally, unlawfully, recklessly, unfairly and/or negligently failed to do so. Instead, Defendants shipped and continue to ship massive quantities of

⁹⁰ Jeff Overley, *AmerisourceBergen Subpoenaed by DEA Over Drug Diversion* (Aug. 9, 2012), LAW360, available at <https://www.law360.com/articles/368498/amerisourcebergen-subpoenaed-by-deaover-drug-diversion>.

⁹¹ Eric Eyre, *Cardinal Health, AmerisourceBergen agree to settle WV pain pill lawsuit* (Dec. 27, 2016), Charleston Gazette-Mail, available at https://www.wvgazettemail.com/news/cops_and_courts/cardinal-health-amerisourcebergen-agree-to-settle-wv-pain-pill-lawsuit/article_3bb37793-5a00-5ae9-9a32-3b7690b5ff67.html.

1 prescription opioids into Washington despite knowing that opioids are highly
2 addictive, that there is an epidemic of opioid abuse in Washington and across the
3 country, and that the opioid epidemic has led to thousands of deaths, widespread
4 dependence and addiction, and other severely negative consequences in the
5 communities touched by the epidemic.

6 4.85 Even using conservative, Defendant-friendly definitions of
7 “suspicious orders,” Defendants are each responsible for shipping tens of
8 thousands of suspicious orders into Washington.

9 4.86 Between 2006 and 2014, the most recent year for which the State of
10 Washington has access to data, McKesson shipped, at a minimum, 142,629
11 suspicious orders into Washington.⁹² The actual number of suspicious orders is
12 almost certainly much higher.

13 4.87 Between 2006 and 2014, the most recent year for which the State of
14 Washington has access to data, Cardinal shipped, at a minimum, 87,754
15 suspicious orders into Washington. The actual number of suspicious orders is
16 almost certainly much higher.

17 4.88 Between 2006 and 2014, the most recent year for which the State of
18 Washington has access to data, AmerisourceBergen shipped, at a minimum,
19 38,380 suspicious orders into Washington. The actual number of suspicious
20 orders is almost certainly much higher.

21 ⁹² These numbers are derived from Washington’s statistical analysis of ARCOS data
22 obtained from the DEA pursuant to a Memorandum of Understanding. The ARCOS database
 is confidential to the DEA. The State of Washington did not have access to this data until it
 entered into its MOU with the DEA on May 21, 2018.

1 4.89 On information and belief, Defendants have fulfilled these
2 suspicious orders without engaging in adequate due diligence to ensure that these
3 orders were not likely to be diverted into illegitimate channels.

4 4.90 On information and belief, many of these suspicious orders were in
5 fact diverted to illegitimate channels, contributing to Washington's opioid
6 epidemic.

7 4.91 On information and belief, the vast majority of these suspicious
orders were never reported to the DEA.

8 4.92 On information and belief, to the extent Defendants internal
9 monitoring systems flagged orders as potentially suspicious based on their size,
10 frequency, or deviation from normal patterns, Defendants nonetheless routinely
11 granted waivers, permitting these orders to ship without adequate due diligence
12 or reports to the DEA.

13 4.93 On information and belief, from 2014 forward, Defendants have
14 continued their well-established patterns of shipping thousands of suspicious
15 orders annually into Washington, without conducting adequate due diligence and
16 without reporting the vast majority of these suspicious orders to the DEA,
17 resulting in substantial diversion of prescription opioids into illegitimate
18 channels, and fueling Washington's opioid epidemic.

19 4.94 Defendants breached their duties under the CSA and Washington
20 law to maintain effective controls against diversion of prescription opioids. 21
U.S.C. § 823(b)(l); 21 C.F.R. § 1301.74(a); WAC 246-879-050; WAC 246-879-
21 080; RCW 69.50.303, 304.

1 4.95 Defendants breached their duties under the CSA and Washington
2 law to report suspicious orders to the DEA. 21 C.F.R. § 1301.74(b); WAC 246-
3 879-050; WAC 246-887-020.

4 4.96 Defendants have breached their common-law duties to exercise
5 reasonable care in the conduct of their business by shipping dangerous amounts
6 of opioids into Washington, without taking adequate measures to avoid their
7 diversion into illegitimate channels. Such measures should have included, among
8 other things, identifying potentially suspicious orders, refusing to fill suspicious
9 orders without conducting due diligence to ensure that the orders were not likely
10 to be diverted, reporting suspicious orders to the DEA, and conducting due
11 diligence into each and every one of its customers to ensure that all customers
were engaged in legitimate, lawful business.

12 4.97 Each Defendant knew or should have known that the quantity of
13 opioids it shipped into Washington far exceeded what could be consumed for
14 medically necessary purposes in Washington, especially given that each
15 Defendant knew it was not the only opioid distributor shipping drugs into
16 Washington.

17 4.98 Defendants breached their duty to avoid creating a public
18 nuisance in the State of Washington by shipping unreasonable quantities of
19 highly addictive, dangerous opioids into the State without engaging
20 reasonable steps to ensure that those drugs would not be diverted into
21 illegitimate channels where they would fuel a massive public health crisis.

1 4.99 Defendants' breach of their duties contributed to an illegal
2 market for opioids in Washington, increased demands for prescription and
3 illicit opioids, and the worst man-made epidemic in U.S. history.

4 **G. Washington State Has a Public Policy Interest in Reducing Opioid
5 Addiction and Abuse.**

6 4.100 Washington State's consumer protection statute and common law
7 protect consumers from the kind of unfair conduct that Defendants employed in
8 recklessly and negligently flooding our state with opioids in spite of growing and
9 irrefutable evidence of widespread abuse and negative impacts.

10 4.101 Washington State has a strong public policy to preserve and protect
11 the health and welfare of its citizens by ensuring high-quality health care and
12 preventing abuse of prescription and non-prescription drugs.

13 4.102 Washington regulates the practice of medicine because "the health
14 and well-being of the people of this state are of paramount importance." RCW
15 18.71.003.

16 4.103 Washington has a strong public policy interest in preventing opioid
17 addiction and abuse. Washington has categorized opioids as Schedule II drugs,
18 RCW 69.50.206(b)(1), meaning that they have "a high potential for abuse,"
19 which "may lead to severe psychological or physical dependence."⁹³

20 4.104 To further its public policy, Washington has taken steps to regulate
21 opioid use. Washington's workers compensation system revealed the disturbing
22 trend. Between 1996 and 2002, opioid prescriptions in the system increased

22 ⁹³ RCW 69.50.205(a)(1) & (3).

1 dramatically and included a 50 percent increase in the average daily morphine
2 milligram equivalents (MME) taken by injured workers.⁹⁴

3 4.105 By 2000, the Department of Labor & Industries noted an alarming
4 rise in overdose deaths.⁹⁵ The Department of Health conducted a manual review
5 of all opioid overdose death certificates, and found an increase in the number of
6 overdose deaths involving prescription opioids from 24 in 1995 to 351 in 2004.
7 By 2006, the CDC had identified Washington to be in the highest tertile of
8 mortality (10.8 deaths/100,000)⁹⁶ from unintentional drug overdoses in the
9 United States. At that same time, approximately 10,000 Washington patients in
10 public insurance programs were taking at least 120 milligrams per day morphine
equivalent dosing.⁹⁷

11 4.106 Accordingly, Washington acted.

12 4.107 Amongst other things, in March 2007, Washington became the first
13 jurisdiction in the country to issue guidelines recommending caution in using
14 high-dose opioids.⁹⁸

15 4.108 In 2009, the Attorney General's Office conducted a survey regarding
16 the guidelines, and in 2010, the Washington State Agency Medical Directors'

17 ⁹⁴ Franklin, *A Comprehensive Approach*, at 464, citing to n16.

18 ⁹⁵ *Id.*

19 ⁹⁶ Franklin, *A Comprehensive Approach*, at 464, citing to n14.

20 ⁹⁷ Franklin, *A Comprehensive Approach*, at 464; Strong epidemiological studies now
support a dosing threshold or range around 80 to 100 milligrams per day. Franklin, *A
Comprehensive Approach*, at 465, citing to n27-29.

21 ⁹⁸ Franklin, *A Comprehensive Approach*, at 464, citing to n18. In 2006 a consortium of
all WA agencies that purchase or regulate health care (the Agency Medical Directors' Group
(AMDG) collaborated with 15 WA pain management experts (the Clinical Advisory Group) to
develop an opioid prescribing guideline.

1 Group (AMDG), issued updated guidelines that provided tools for calculating
2 dosages, screening for substance abuse, mental health, and addiction, clinical
3 tools, and patient education materials and resources.⁹⁹

4 4.109 Also in 2010, the Washington Legislature began enacting legislation
5 to address the threat opioids posed to public health. In response to new
6 legislation, Washington medical boards promulgated new standards for opioid
7 prescriptions for the treatment of chronic non-cancer pain.

8 4.110 The new guidelines had a significant effect. Prescription opioid
9 overdose death rates in Washington declined by 27 percent from 2008 to 2012,
10 and overdose hospitalization rates declined for the first time in 2012. The
11 percentage of Washington residents who have used prescription pain medication
12 non-medically in the past year declined from 6.2 percent in 2009–2010 to 5.1
percent in 2011–2012.¹⁰⁰

13 4.111 The decline in prescription overdose deaths has, however, been
14 more than offset by a corresponding rise in heroin overdose deaths. The rise in
15 illicit opioid deaths is a foreseeable consequence of Defendants' conduct in
16 flooding the State with addictive opioid pills. Nearly 80 percent of heroin users
17 report using prescription opioids before beginning heroin use.¹⁰¹ Once the

18 ⁹⁹ In June 2015, the AMDG released another update to the Interagency Guidelines.
19 Washington Secretary of Health John Wiesman noted that "Washington and many other states
20 are in the midst of an epidemic of opioid misuse, abuse, and overdose," and warned that
"although opioids can be a useful option for pain management, their inappropriate use can
result in significant harms, including addiction and death."

21 ¹⁰⁰ Franklin, *A Comprehensive Approach*.

22 ¹⁰¹ National Institute on Drug Abuse, *Prescription opioid use is a risk factor for heroin
use* (Jan. 2018), available at <https://www.drugabuse.gov/publications/research-reports/relationship-between-prescription-drug-heroin-abuse/prescription-opioid-use-risk-factor-heroin-use>.

1 widespread and unchecked availability of prescription opioids had created a
2 significant population of physically dependent patients, efforts to restrict
3 prescribing inevitably pushed those patients into finding alternate sources of
4 opioids. Defendants knew or should have known that patients physically
5 dependent on the opioids they provided would engage in illicit use when they
6 were no longer able to obtain legal prescriptions.

7 4.112 In addition to medical guideline and legislative action, Washington's
8 consumer protection laws also prohibit Defendants from engaging in unfair acts
9 or practices in the conduct of any trade. As is detailed below, Defendants'
10 widespread distribution of opioids, without effective measures to prevent
11 diversion, was, in the context of the addictive and deadly properties of opioids,
12 unfair to the citizens of Washington.

12 **H. Opioids Have Severely Impacted Washington State.**

13 4.113 Opioid use, morbidity, and mortality have increased exponentially
14 nationwide and across Washington State in the years since Defendants first began
15 flooding the State with opioids, including thousands of orders that should have
16 been flagged as suspicious. Prescriptions and sales of opioids in Washington
17 skyrocketed more than 500% between 1997 and 2006.¹⁰²

18 4.114 In 2011, at the peak of overall sales in Washington, more than 112
19 million daily doses of all prescription opioids were dispensed in the state—
20
21

22 102 Franklin, *A Comprehensive Approach*.

1 enough for a 16-day supply for every woman, man, and child in the state.¹⁰³
2 Although rates of prescription drugs have declined somewhat, they remain
3 dangerously high, with 68.2 prescriptions per 100 Washingtonians in 2015.¹⁰⁴

4 4.115 Nearly one-fourth of all Washington residents received at least one
5 opioid prescription in 2014.¹⁰⁵ Even as prescription rates decline, in 2016 there
6 were still seven counties in which enough opioid prescriptions were dispensed for
7 every person in that county to have one, and in 2017, four.¹⁰⁶

8 4.116 According to the CDC, between 1999 and 2017 more than 218,000
9 people died in the United States from prescription-related overdoses.¹⁰⁷ There
10 have been more than 10,000 deaths attributable to any opioid in Washington
11 alone since turn of the 21st century.¹⁰⁸

12
13 ¹⁰³ Connelly, Joel, *Judge OKs state's suit against opioid maker*, Seattle PI (Apr. 6.
14 2018), available at <https://www.seattlepi.com/local/politics/article/Judge-gives-go-ahead-to-suit-against-opioid-12813562.php>.
15

16 ¹⁰⁴ National Institute on Drug Abuse, *Washington Opioid Summary* (Feb. 2018),
17 available at <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-summaries-by-state/washington-opioid-summary>.
18

19 ¹⁰⁵ Washington State Department of Health, *PDMP County Profiles 2014: Executive
20 Summary* (May 2017), available at <http://www.doh.wa.gov/Portals/1/Documents/2600/PMPcountyProfiles/630-126-CountyProfilesExecutiveSummary2014.pdf>.
21

22 ¹⁰⁶ Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2017*
(Jul. 31, 2017), available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2017.html>;
23 Centers for Disease Control and Prevention, *U.S. County Prescribing Rates, 2016* (Jul. 31,
24 2017), available at <https://www.cdc.gov/drugoverdose/maps/rxcounty2016.html>.
25

26 ¹⁰⁷ Centers for Disease Control and Prevention, *Prescription Opioid Data* (Dec. 2018),
27 available at <https://www.cdc.gov/drugoverdose/data/prescribing.html>.
28

29 ¹⁰⁸ Washington State Department of Health, *Washington State Residents Drug
Overdose Quarterly Report* (Mar. 2019), available at
30 https://www.doh.wa.gov/Portals/1/Documents/8300/wa_lhj_quarterly_report_18_1_2_pub.htm.
31

a. Overall, the majority of drug overdose deaths in Washington (more than 6 out of 10) involve an opioid.¹⁰⁹

b. Overdose deaths—specifically opioid overdose—have overtaken those causes that have traditionally had the highest rates of accidental death. Between 2014 and 2017, the number of overdose deaths in Washington (2,915) surpassed the number of deaths in car accidents (2,132) and nearly matched the number of deaths from firearms—suicide, homicide, and accidental (2,955).¹¹⁰

c. Drug-caused deaths involving opioids increased 77% statewide between 2002–2004 and 2015–2017, with increases in most counties. The total number of drug-caused deaths involving opioids in 2017 was 798, with over 8,000 deaths total from 2006–2017.¹¹¹ The annual rate of opioid deaths has remained relatively steady since 2006.¹¹² While prescription-opioid-related deaths have decreased in that timeframe, heroin and fentanyl deaths have increased correspondingly.¹¹³

¹⁰⁹ Rudd, *Increases 2010-2015*.

¹¹⁰ Alcohol & Drug Abuse Institute, University of Washington, *Opioid trends across Washington state* (Oct. 9, 2018), available at, <https://adai.washington.edu/WAdata/deaths.htm>; Washington State Department of Health, *DOH Opioid-Related Deaths in Washington State, 2006-2016* (May 2017), available at <https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf>; Insurance Institute for Highway Safety Highway Loss Data Institute, *General statistics Crashes took 37,133 lives in the U.S. in 2017* (2017), available at <https://www.iihs.org/iihs/topics/t/general-statistics/fatalityfacts/state-by-state-overview/>; Centers for Disease Control and Prevention, *Firearm Mortality by State* (Jan. 2019) available at https://www.cdc.gov/nchs/pressroom/sosmap/firearm_mortality/firearm.htm.

¹¹¹ Washington State Department of Health, *DOH Opioid-Related Deaths in Washington State, 2006-2016* (May 2017), available at <https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf>.

112 *Id.*

113 *Id.*

1 d. In King County, prescription-type opioid trends are down somewhat
2 from peaks around 2010, however prescription-type opioid-involved deaths are
3 persisting at elevated rates and are second only to heroin in terms of most
4 common drugs identified in fatal overdoses.¹¹⁴

5 4.117 Geographic areas with higher per-capita rates of opioid prescribing
6 show a strong correlation with higher overdose rates.

7 4.118 The death rates in Washington are geographically disparate and are
8 concentrated in the counties with the highest rates of opioid prescriptions. For
9 instance:

10 a. In 2014, Asotin County in the southeastern corner of the state had a
11 rate of opioid substance use of 286.9 patients prescribed opioids per 1,000
12 residents and a corresponding 12.4 deaths attributable to any opioid per 100,000
13 residents between 2015 and 2017. That overdose death rate was a more than
14 270% increase from 2002 to 2004. Similarly, Cowlitz County in the southwestern
15 corner of the state had a rate of opioid substance use of 273 patients prescribed
16 opioids per 1,000 residents in 2014, and a corresponding 12.06 deaths
17 attributable to any opioid per 100,000 residents between 2015 and 2017. This
18 pattern can be seen repeated in many Washington counties.

19 4.119 Clallam, Cowlitz, King, Asotin, Ferry, Lincoln, Columbia, Walla
20 Walla, Benton, Pacific, Gray's Harbor, Jefferson, Pierce, Mason, and Snohomish
21 counties have opioid overdose rates higher than the state average. While not
22 located in the one of the four corners, Snohomish County has experienced a

¹¹⁴ Alcohol & Drug Abuse Institute, University of Washington, *Opioid trends across Washington state* (Oct. 9, 2018), available at, <https://adai.washington.edu/WAdata/deaths.htm>

1 68.8% increase in deaths involving any opiate between 2002 and 2004 and 2015
2 and 2017.

3 4.120 The scope of human suffering and economic cost of opioids on
4 Washington reverberates far beyond overdose mortality rate. The State spends
5 significant public resources on medical services, law enforcement, corrections,
6 workers' compensation, diversion programs, prosecution, probation, treatment,
and child welfare.

7 a. The cumulative rate of opioid-related inpatient hospital and clinic
8 stays increased by 60.1 percent in Washington between 2009 and 2014, the fourth
9 greatest increase in the nation.¹¹⁵ That rate of 313.2 opioid-related inpatient stays
per 100,000 in population placed Washington eighth in the nation.¹¹⁶

10 b. The Washington State Toxicology Laboratory, housed within
11 Washington State Patrol, has received a significant increase in the number of
12 cases submitted for testing in recent years by approximately 1,000 cases per year
13 since 2013. The increased caseload results in a backlog of samples waiting to be
14 tested.¹¹⁷

15 c. Crime lab data for police evidence testing for opioids indicate an
16 85% increase statewide between 2002–2004 and 2011–2013, with increases in
17

18 ¹¹⁵ Audrey J. Weiss et al., *Opioid-Related Inpatient Stays and Emergency Department*
19 *Visits by State, 2009-2014* (Dec. 15 2016, revised Jan. 26, 2017), Healthcare Cost and
Utilization Project (HCUP), available at <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb219-Opioid-Hospital-Stays-ED-Visits-by-State.jsp>.

20 ¹¹⁶ *Id.*

21 ¹¹⁷ Washington State Department of Health, *Reducing the Supply of Illegal Opioids in*
22 *Washington State* (Nov. 2017), available at
<https://www.doh.wa.gov/Portals/1/Documents/2300/2017/ReducingSupplyIllegalOpioidsInWA-A-AAG.pdf>

most counties.¹¹⁸ Police evidence testing results show that oxycodone has consistently been the most common prescription-type-opioid detected in all years.¹¹⁹

4 d. Publicly funded drug treatment admissions for opioids as the primary drug increased 197% statewide, with increases in 38 of 39 counties.¹²⁰

5 4.121 Unfair and negligent distribution of opioids by Defendants also has a
6 significant detrimental impact on children in Washington. Adolescent misuse of
7 prescription-type-opioids is very important because it is the peak period in life
8 when people first misuse opioids.¹²¹ The statewide saturation of opioids has
9 given young children access to opioids, nearly all of which were prescribed for
adults in their household or to the children by dentists.¹²²

a. The 2016 Healthy Youth Survey revealed that a significant portion of Washington students misuse prescription drugs—about 4,500 twelfth graders

¹¹⁸ Alcohol and Drug Abuse Institute, University of Washington, *Opioid Trends Across Washington State* (Apr. 2015), available at <https://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf>.

¹¹⁹ Alcohol and Drug Abuse Institute, University of Washington, *2016 Drug Use Trends in King County, Washington* (Jul. 2017), available at <http://adai.uw.edu/pubs/pdf/2016drugusetrends.pdf>.

¹²⁰ Alcohol and Drug Abuse Institute, University of Washington, *Opioid Trends Across Washington State* (April 2015), available at <https://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf>.

¹²¹ Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Alcohol and Drug Abuse Institute, University of Washington, (Feb. 2017), p. 5, citing to Meier et al., 2012 available at <https://www.tpchd.org/home/showdocument?id=2002>.

¹²² Washington State Department of Health, *Reducing the Supply of Illegal Opioids in Washington State* (Nov. 2017), p. 7, 13-14, available at <https://www.doh.wa.gov/Portals/1/Documents/2300/2017/ReducingSupplyIllegalOpioidsInWA-AAG.pdf>.

1 use prescription opioids to get high in any given month, and about 3,600 have
2 tried heroin at least once.¹²³

3 b. Washington dentists are the biggest prescribers of opioids to youth,
4 prescribing more than 13,000 pills to youth age 14–19 in one six-month period in
5 2015. For comparison, emergency medicine providers, the second highest
6 prescribers, issued prescriptions for approximately 2,500 pills in the same period.

7 c. While Healthy Youth Survey data for King County tenth graders
8 indicate a significant decline in the proportion reporting past-month use of
9 prescription-type-opioids to get high, that decline is being offset somewhat by
10 increased rates of heroin use. In 2006, 10% of King County tenth graders reported
11 past- month use of prescription-type-opioids to get high; that number has steadily
12 declined in bi-annual surveys to 4% in 2014 and the same proportion in 2016.¹²⁴
13 However, in 2016 there was a strong association between reporting use of
14 prescription-type-opioids to get high and having ever used heroin (26%),
15 compared to only 2% reporting ever having used heroin if they had not used
16 prescription-type- opioids to get high.

17 4.122 Even infants have not been immune to the impact of opioid abuse.
18 There has been a dramatic increase in the number of infants who are born
19 addicted to opioids due to prenatal exposure and suffer from neonatal abstinence
20 syndrome (NAS), which can occur in an infant exposed in utero to addictive,
21 illegal or prescription drugs.

22 ¹²³ 2016 Washington State Healthy Youth Survey, *Data Brief: Prescription Drugs and Opiates*, Washington State Department of Health (2016), available at <http://www.doh.wa.gov/Portals/1/Documents/8350/160-NonDOH-DB-Opiates.pdf>.

a. Neonatal abstinence syndrome (NAS) can occur in an infant exposed in utero to addictive, illegal or prescription drugs. Babies born with NAS may experience a variety of withdrawal symptoms, medical complications and have prolonged hospital stays. According to the Centers for Disease Control and Prevention, the incidence rate of NAS in Washington State increased from a rate of 1.5 for every 1,000 hospital births in 1999 to a rate of 7.9 for every 1,000 hospital births in 2013.¹²⁵ In Washington, prenatal exposure to opioids increased from 11.5 percent of all drug-exposed neonates in 2000 to 24.4 percent in 2008, and 41.7 percent of infants diagnosed with NAS were exclusively exposed to opioids.¹²⁶

4.123 Opioid use has had a significant impact on Washington's child welfare system. Parental substance abuse is a major risk factor for child fatalities, child maltreatment, and involvement with the child welfare system.

a. From calendar year 2013 to 2016, the Office of the Family & Children's Ombuds identified 33 maltreatment related fatalities of children ages zero to three years where a caregiver's opiate use was a known risk factor.¹²⁷

¹²⁵ Jean Y. Ko et al., *Incidence of Neonatal Abstinence Syndrome – 28 States, 1999–2013*, 65(31):799–802, Morbidity and Mortality Weekly Report (Aug., 2016), available at <https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm>.

¹²⁶ Washington Office of the Family and Childrens' Ombuds, *Child Fatalities and Near Fatalities in Washington State*, (Aug. 2017), available at <http://ofco.wa.gov/wp-content/uploads/OFCO-Report-Child-Fatalities-and-Near-Fatalities-in-Washington-State-2016.pdf>, p.21-22, citing to *Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care*, (2014), available at <http://www.astho.org/prevention/nas-neonatal-abstinence-report>.

¹²⁷ Washington Office of the Family and Childrens' Ombuds, *Child Fatalities and Near Fatalities in Washington State*, (Aug. 2017), available at <http://ofco.wa.gov/wp-content/uploads/OFCO-Report-Child-Fatalities-and-Near-Fatalities-in-Washington-State-2016.pdf>.

1 b. Upon information and belief, a review of a representative sample of
2 dependency petitions filed 2014–2016 in Snohomish County found that in more
3 than 95% of cases where children were removed from the home due to parental
4 drug use, the drug involved was an opioid.

5 c. Children removed from their home as a result of parental substance
6 abuse are likely to remain in foster care longer and have significantly higher rates
7 of adoption than those in foster care for other reasons.¹²⁸ A higher rate of
8 adoption indicates that children removed from their homes remain in foster care
9 longer and are less likely to exit from foster care to reunification with biological
parents.

10 4.124 The initial rise in prescription-type opioids came while heroin
11 deaths, crime lab cases, and treatment rates were on the decline, and the recent
12 decline for prescription-type opioids comes as heroin returns to prominence and
13 illicit fentanyl emerges as a threat. Following the statewide peak in 2011, the
14 number of prescriptions of opioids has declined and correspondingly so has the
15 rate of overdose deaths attributed to prescription opiates. The overall rate of
16 overdose in Washington State, however, has increased in recent years because of
17 an increase in heroin and fentanyl use and overdose deaths attributed to heroin
18 and fentanyl.

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22 ¹²⁸ *Id.* at p.20, citing to Karen E. Hanson et al., *Family-Based Recovery: An Innovative In-Home Substance Abuse Treatment Model for Families with Young Children*.

1 4.125 Many individuals who use heroin, and the majority of young adults
2 who use heroin, report using prescription-type opioids prior to switching to
3 heroin.¹²⁹

4 4.126 In a 2014 study, 5% of Pierce County 10th graders reported lifetime
5 heroin use and current painkiller use “to get high”. While most students reported
6 using neither, 3% had tried heroin, 4.4% reported using painkillers only, and 1%
7 reported using both. Among those who tried heroin, 34.7% reported the use of
8 painkillers, while only 4.5% who had not tried heroin reported the use of
9 painkillers. Nearly one in five students who reported painkiller use during the last
month in the study also admitted to having used heroin in the past.¹³⁰

10 4.127 Heroin indicators remain at high levels across all measures:

- 11 a. Heroin deaths more than doubled between 2010 and 2015.¹³¹
- 12 b. Heroin was the most common drug reported as primary in 2016,
13 accounting for 31% of all treatment admissions, a numerical and proportional
14 increase compared to 2012.¹³²

15

16 ¹²⁹ K. Michelle Peavy et al., “*Hooked on” Prescription-Type Opiates Prior to Using*

17 *Heroin: Results from a Survey of Syringe Exchange Clients*, 44(3) Journal Of Psychoactive

18 Drugs (Aug. 2012); Emily R. Cedarbaum & Caleb J. Banta-Green, *Health behaviors of young*

adult *heroin injectors in the Seattle area*, 158 Drug And Alcohol Dependence (Nov. 2015).

19 ¹³⁰ Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Alcohol and Drug Abuse

Institute, University of Washington, (Feb. 2017), p. 5, available at

<https://www.tpchd.org/home/showdocument?id=2002>.

20 ¹³¹ Washington State Department of Health, *Opioid-related Deaths in Washington*

State, 2006-2016, (May 2017), available at

[http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-](http://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf)

SummaryOpioidOverdoseData.pdf.

21 ¹³² Caleb Banta-Green et al. *2016 Drug Trends for King County, Washington*, Alcohol

& Drug Abuse Institute, University of Washington, (Jul. 2017), available at

<http://adai.uw.edu/pubs/pdf/2016drugsetrends.pdf>.

1 c. There were more than four calls per day to King County's Recovery
2 Helpline seeking assistance regarding heroin.¹³³ Heroin-related calls to the
3 Recovery Helpline have consistently been the most common drug for calls
4 regarding young adults. There were 476 calls in 2016, similar to prior years. For
5 adults 26 and older, heroin was consistently the second most common substance
6 reported in calls to Recovery Helpline, and there were a total of 1,179 calls in
7 2016 similar to the prior year.¹³⁴

8 d. For adults ages 18–25 admitted to treatment, heroin was numerically
9 and proportionally much more common than other drugs, with a relatively large
10 proportion, 19%, of admissions for heroin ages 18–25.¹³⁵

11 e. In Pierce County, a recent increase in police evidence testing cases
12 and drug overdose deaths is being driven by increases in heroin use.¹³⁶
13 Correspondingly, treatment admissions in Pierce County for heroin and first
14 admissions for heroin have risen precipitously since 2013.

15 4.128 More recently, deaths attributed to highly dangerous illicit fentanyl
16 have skyrocketed in the past few years. While 53 Washingtonians died of
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20 ¹³³ *Id.*
21 ¹³⁴ *Id.*
22 ¹³⁵ *Id.*
23 ¹³⁶ Caleb Banta-Green et al., *Opioid Trends in Pierce County*, Tacoma-Pierce County
24 Health Department (Feb. 2017), available at
25 <https://www.tpchd.org/home/showdocument?id=2002>.

1 || fentanyl overdoses in 2015,¹³⁷ that number ballooned to 81 in the first half of
2 || 2018 alone.¹³⁸

3 4.129 The staggering rise in use of heroin and fentanyl and heroin- and
4 fentanyl-related overdose deaths is a predictable result of the saturation of
5 prescription opioids in Washington.¹³⁹

4.130 Defendants flooded the State with prescription opioids, leading to
6 high rates of opioid dependence. When dependent users are unable to obtain
7 prescription opioids they turn to illicit sources of opiates such as heroin and
8 fentanyl. Defendants knew or should have known that their saturation of the
9 market with opioids would result in increased heroin and fentanyl use in
10 Washington.

I. Defendants Are Responsible for Washington's Opioid Crisis.

12 4.131 As detailed in this complaint, the impacts of opioids on Washington
13 are inextricably linked with Defendants' actions in flooding the State with
14 dangerous and addictive opioids, without taking effective measures to ensure
15 those opioids were not diverted to illegitimate channels.

16 4.132 Defendants systematically ignored their obligations designed to
17 prevent the very harms of prescription drug diversion that came to wreak havoc
18 on our state.

¹³⁷ Mamadou Ndiaye, *Fentanyl Overdose Deaths in Washington State*, Washington State Department of Health (May 5, 2017), available at <https://www.doh.wa.gov/Portals/1/Documents/1600/DOHFentanylReport2017Final.pdf>.

¹³⁸ Ryan Blethen, *Huge rise in overdose deaths, in Washington state and the nation, from fentanyl, which can kill even in tiny doses*, Seattle Times (Dec. 5, 2018), available at <https://www.seattletimes.com/seattle-news/health/overdose-deaths-from-powerful-narcotic-fentanyl-on-the-rise-in-washington/>.

¹³⁹ Franklin, *A Comprehensive Approach*, citing to n45-47.

1 4.133 As a result of Defendants' conduct, opioid use has grown to
2 epidemic proportions and the death rates continue to rise while Defendants
3 continue to flood the State with drugs that it knows are deadly.

4 4.134 The Attorney General asks the court to stop Defendants' unfair,
5 unlawful, reckless, and/or negligent distribution of drugs and to order legal and
6 equitable remedies to begin addressing the opioid epidemic.

V. FIRST CAUSE OF ACTION

(VIOLATIONS OF THE CONSUMER PROTECTION ACT, RCW 19.86)

8 5.1 The State incorporates each of the foregoing paragraphs herein as if set
9 forth in their entirety.

10 5.2 RCW 19.86.020 prohibits “unfair” or “deceptive” acts or practices in
11 trade or commerce.

12 5.3 The distribution and sale of opioids to pharmacies and health care
13 providers in Washington constitutes “trade” or “commerce” defined by RCW
19.86.010(2).

14 5.4 Defendants engaged in unfair acts or practices in the distribution of
15 massive amounts of opioids even as it became clear that opioid addiction had become
16 a health epidemic.

17 5.5 Defendants delivered opioids indiscriminately, including filling tens of
18 thousands of “suspicious orders” they should never have filled, without adequate due
19 diligence or reporting to law enforcement, in violation of federal and state law and
Washington’s clear public policy to curb opioid abuse.

5.6 Defendants engaged in numerous unfair acts or practices, including
the following:

- a. Filling tens of thousands of suspicious orders which they knew or should have known were likely to be diverted into illegitimate channels;
 - b. Failing to conduct adequate due diligence to ensure that they were only filling legitimate orders for legitimate customers;
 - c. Failing to identify potentially suspicious orders;
 - d. Filling orders which their internal monitoring systems flagged as potentially suspicious, without engaging in adequate due diligence; and
 - e. Failing to report suspicious order to law enforcement.

5.7 Defendants' unfair conduct in the distribution and sale of opioids to pharmacies and health care providers in Washington affects the public interest because the opioids were distributed to Washington businesses and ultimately to numerous consumers in Washington, injured numerous Washington consumers, created a public health crisis and a public nuisance, were part of Defendants' very business model and regular course of business operations, and were repeated.

VI. SECOND CAUSE OF ACTION (PUBLIC NUISANCE)

6.1 The State incorporates each of the foregoing paragraphs herein as if set forth in their entirety.

6.2 RCW 7.48.120 provides that:

[n]uisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either annoys, injures or endangers the comfort, repose, health or safety of others, offends decency, or unlawfully interferes with, obstructs or tends to obstruct, or render dangerous for passage, any lake or navigable river, bay, stream, canal or basin, or any public park, square, street or highway; or in any way renders other persons insecure in life, or in the use of property.

1 6.3 Pursuant to RCW 7.48.130, a “public nuisance” is a nuisance that
2 “affects equally the rights of the entire community or neighborhood, although the
3 extent of the damage may be unequal.”

4 6.4 Finally, RCW 7.48.010 defines an “actionable nuisance” to include
5 “whatever is injurious to health or indecent or offensive to the senses.”

6 6.5 Through the actions described above, the Defendants have
7 contributed to and/or assisted in creating and maintaining a condition that is
8 unreasonable and harmful to the health of Washingtonians and/or interferes with
9 the comfortable enjoyment of life in violation of Washington law. For example:

10 a. Opioid use, abuse, and overdose deaths have increased throughout the
11 State.

12 b. Locations such as the offices of high-prescribing health care
13 practitioners and the pharmacies at which their patients fill opioid prescriptions
14 have attracted drug dealers and served as a source of diversion.

15 c. Locations such as abandoned homes and some public spaces have
16 attracted drug traffic, rendering them and the surrounding private property less safe
17 or unsafe. In addition, family medicine cabinets became outlets for diversion and
18 abuse due to over-saturation of the market, and the foreseeable failure to safely
19 dispose of opioids.

20 d. The greater demand for emergency services, law enforcement,
21 addiction treatment, and social services places an unreasonable burden on State
22 and local resources.

1 e. Distributing drugs indiscriminately to customers without conducting
2 due diligence to ensure that those drugs were not likely to be diverted has also
3 created an abundance of drugs available for criminal use and fueled a wave of
4 addiction, abuse, and injury.

5 f. The creation of additional illicit markets in other opiates, particularly
6 heroin and fentanyl. Many users who were initially dependent on prescription
7 opioids and then were unable to obtain or afford prescription opioids turned to
heroin or fentanyl as an alternative, fueling a new epidemic in the process.

8 g. Increased health care costs for individuals, families, and the State.

9 h. Defendants also interfered with enjoyment of the public right by
10 filling and failing to report suspicious orders to law enforcement, allowing health
11 care providers and pharmacies who were profitable to Defendants but problematic
12 for the public health to continue prescribing increasing numbers of opioids
13 throughout the State.

14 6.6 The public nuisance created by Defendants' actions is substantial and
15 unreasonable—it has caused significant harm to communities across Washington,
16 outweighing any offsetting benefit. Defendants knew or should have known that
17 their careless distribution of millions of opioid pills throughout Washington would
create a public nuisance.

18 6.7 Defendants' actions described above were a substantial factor in
19 opioids becoming widely available, used, and all too often abused. These actions
20 were a substantial factor in rogue pharmacies' and health care providers' ability to
21 access and then prescribe opioids that were not medically necessary.

1 6.8 But for Defendants' actions, opioid use would not have become so
2 widespread, and the enormous public health hazard of opioid overuse, abuse, and
3 addiction that now exists would have been averted. Defendants' actions have and
4 will continue to injure and harm many residents throughout the state, including
5 patients with chronic non-cancer pain who take opioids, their families, and their
6 communities at large.

7 6.9 The public nuisance and associated financial and economic losses
8 were foreseeable to Defendants, who knew or should have known that their unfair
9 business practices were creating a public nuisance.

10 6.10 Defendants are liable for a public nuisance because they acted without
11 express authority of a statute in recklessly pumping massive quantities of opioids
12 into Washington without taking adequate steps to prevent against diversion.

13 6.11 The health and safety of Washington residents, including those who
14 use, have used or will use opioids, as well as those affected by users of opioids, is
15 a matter of great public interest and of legitimate concern to the State, whose duty
16 to protect the health, safety, and well-being of its residents is paramount.
17 Washington and its residents have a right to be free from conduct that endangers
18 their health and safety. Defendants' deceptive marketing and unfair business
19 practices interfered in the enjoyment of this public right by the State and its
20 citizens.

21 6.12 Pursuant to RCW 7.48.020 and 7.48.180, the State seeks an order that
22 provides for abatement of the public nuisance Defendants have created, enjoining

1 Defendants from future violations of RCW Chapter 7.48, and awards the State
2 damages in an amount to be determined at trial.

3

4 **VII. THIRD CAUSE OF ACTION**
5 **(COMMON LAW NEGLIGENCE)**

6 7.1 The State incorporates each of the foregoing paragraphs herein as if
7 set forth in their entirety.
8

9 7.2 Under Washington law, a cause of action arises for negligence when
10 defendant owes a duty to a plaintiff and breaches that duty, and proximately
11 causes the resulting injury.
12

13 7.3 Defendants owed a duty of care to the citizens of Washington,
14 including but not limited to exercise reasonable care in the distribution of highly
15 addictive drugs like opioids. Defendants knew or should have known that their
16 affirmative conduct in shipping massive quantities of opioids into the State,
17 without taking adequate measures to prevent diversion, created an unreasonable
18 risk of harm.
19

20 7.4 A reasonably prudent distributor would be aware that filling
21 suspicious orders for opioids, without conducting due diligence or informing the
22 DEA, would result in the severe harm of addiction for large numbers of
Washingtonians and that increasing the numbers of prescription opioids available
in the market would lead to massive harm to the public including increased
hospitalizations, overdoses, and deaths.
23

1 7.5 In fact, each of the Defendants have previously been sanctioned for
2 the conduct at issue in this suit, and have acknowledged their obligations to adopt
3 measures to prevent diversion, but failed to do so.

4 7.6 By distributing massive amounts of opioids without adopting
5 effective controls to prevent their diversion into illegitimate channels, Defendants
6 breached their duty of reasonable care as distributors of dangerous opioids and
dramatically increased the risk for public harm.

7 7.7 Defendants' conduct was a proximate cause of increased opioid use
8 and abuse along with the inevitable and foreseeable consequences and public
9 harms.

10 7.8 As a direct and proximate cause of Defendants' unreasonable and
11 negligent conduct, Washington has suffered and will continue to suffer harm, and
12 is entitled to damages in an amount determined at trial.

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VIII. PRAYER FOR RELIEF

Wherefore, the State prays for the following relief:

8.1 A declaration that Defendants' acts described above are unfair acts or practices in trade or commerce, affecting the public interest, and in violation of the Consumer Protection Act, RCW 19.86;

8.2 An injunction pursuant to RCW 19.86.080(1) enjoining Defendants from engaging in any acts that violate the Washington Consumer Protection Act, including, but not limited to, the unfair acts and practices alleged herein;

8.3 An order necessary to restore to any person an interest in any moneys or property, real or personal, which may have been acquired by means of an act prohibited by the Consumer Protection Act, pursuant to RCW 19.86.080(2):

8.4 An award of a civil penalty in the amount of \$2,000.00 for each and every violation of Washington's Consumer Protection Act, pursuant to RCW 19.86.140;

8.5 An award of the State's reasonable costs and attorney's fees incurred in this action, pursuant to RCW 19.86.080(1);

8.6 An order requiring Defendants to abate the public nuisance that they created;

8.7 An award of damages in an amount determined at trial for injury sustained by the State as a result of Defendants' unreasonable and negligent conduct;

1 8.8 Equitable relief requiring restitution and disgorgement of the
2 revenues wrongfully obtained from sale of extended release opioids as a result of
3 Defendants' wrongful conduct;

4 8.9 An award of pre-judgment and post-judgment interest, as provided
5 by law; and

6 8.10 Any other and further relief the Court deems just and equitable.

7 DATED this 12th day of March, 2019.
8

9 ROBERT W. FERGUSON
10 Attorney General

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